Division of Medical Assistance	**Clinical Coverage Policy No. 11A-5**
High Dose Chemotherapy +/- Total Body Irradiation Including Allogeneic Stem Cell Support For Genetic Diseases and Acquired Anemias	**Original Effective Date: July 1, 1987** **Revised Date: December 1, 2005**

Introduction

Specialized services for blood and marrow transplantation include both autologous and allogeneic stem cell transplants. The principle underlying stem cell transplantation is the transfer of hematopoietic stem cells after the administration of high dose chemotherapy, with or without radiotherapy. The source of hematopoietic stem cells can be either bone marrow (bone marrow transplants, BMTs) or the peripheral blood (peripheral blood stem cell transplants, PBSCTs). The fetal blood harvested from the placenta and umbilical cord is also a stem cell source (cord blood transplants).

Autologous stem cell support/ transplantation (previously referred to as an autologous bone marrow transplant) involves re-infusing intravenously a portion of the patient's own stem cells to rescue the patient and re-establish his/her bone marrow which has been eradicated by high dose chemotherapy/radiotherapy used to destroy malignant cells. Autologous stem cells can be harvested from bone marrow or from circulating blood through the process of pheresis. Tandem transplantation is defined as two or more planned courses of high dose chemotherapy with stem cell support.

Allogeneic stem cell transplantation involves the administration of blood or marrow stem cells from either a family member (usually an HLA matched sibling but on occasions a haploidentical relative) or a matched unrelated donor following administration of chemo/radiotherapy. The genetic disparity between donor and recipient means that allogeneic transplantation is associated with a number of life-threatening complications including graft-versus-host disease, graft rejection and delayed immune reconstitution. Immunologic compatibility between donor and patient is a critical factor for achieving a good outcome. Cord blood donors do not have to be matched as closely as bone marrow or peripheral blood progenitor cell donors.

The following policy contains the minimal criteria for stem cell transplants. Additional justification may be required at the discretion of the Division of Medical Assistance Prior Approval staff.

1.0 Definition of the Procedure

High dose chemotherapy with/without total body irradiation involves the administration of cytotoxic agents using doses several times greater than the standard therapeutic followed by infusion of allogeneic stem cells.

Genetic diseases and acquired anemias are primarily marrow based, which are not malignant, but are still considered fatal if left untreated, (i.e., aplastic anemia, or immunodeficiencies) or are associated with severe morbidity in some sub-sets of patients (i.e., sickle cell disease). Inborn errors of metabolism (i.e., mucopoly-saccharidoses, leukodystrophies, lysosomal storage diseases, mucolipidoses) are congenital defects in one of the enzymes critical to metabolism. Thalassemia, which is a group of inherited disorders of hemoglobin metabolism can range from minimal, to fatal anemia or fatal sequelae of cardiac, pulmonary, and hepatic iron deposits.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at http://www.dhhs.state.nc.us/dma/prov.htm.

3.0 When the Procedure is Covered

The N.C. Medicaid program covers high dose chemotherapy with TBI and allogeneic stem cell support for genetic diseases and acquired anemia for patients with the following conditions who meet the specified criteria:

3.1 Sickle Cell Anemia

1. Children or young adults with a history of prior stroke, or at increased risk of a stroke, or end organ damage
2. Factors related to increased risk of stroke, or end organ damage, i.e., recurrent chest syndrome, vaso-occlusive crisis, chronic transfusion therapy, or red blood cell alloimmunization
3. Human Leukocyte Antigens (HLA)-identical related donor

3.2 Severe Aplastic Anemia

1. Congenital: Fanconi's anemia, Diamond-Black-fan syndrome
2. Acquired forms: secondary to drug or toxin exposure
3. Platelets less than 20×10^9/L
4. Granulocytes less than 0.5×10^9/L
5. Reticulocytes less than 1%
6. Failed antihymocyte globulin therapy

3.3 Homozygous Beta Thalassemia

1. Thalassemia major
2. Cooley's anemia

3.4 Mucopolysaccharidoses

1. Hunter's
2. Hurler's
3. Sanfilippo
4. Maroteaux-Lamy variants
5. Must be neurologically intact

3.5 Mucolipidoses

1. Gaucher's disease
2. Globoid cell leukodystrophy
3. Adrenoleukodystrophy
4. Metachromatic leukodystrophy
5. Patients with the above, must have failed conventional therapy, such as diet and enzyme replacement
6. Must be neurologically intact

3.6 Infantile malignant osteopetrosis

1. Alber's-Schonberg disease
2. Marble bone disease

3.7 Other Conditions as Follows

1. Kostman's syndrome
2. Leukocyte adhesion deficiencies
3. X-linked lymhoproliferative syndrome
4. Severe combined immunodeficiencies
5. Wiskott-Aldrich syndrome

3.8 Individual Evaluation

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage.

4.0 When the Procedure is Not Covered

The N.C. Medicaid program does not cover high dose chemotherapy and allogeneic stem cell support for genetic diseases and acquired anemia for other than what is listed in **Section 3.0**.

4.1 Substance Abuse

History of or active substance abuse - must have documentation of substance abuse program completion plus six months of negative sequential random drug screens.

Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

4.2 Psychosocial History

Psychosocial history that would limit the ability to comply with medical care pre and post transplant.

4.3 Medical Compliance
Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

4.4 Individual Evaluation
Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All services must be prior approved by DMA.

If prior approval has been given for stem cell transplants, donor expenses (**procuring, harvesting, short-term storing and all associated laboratory costs**) are covered.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of the procedure.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 1987

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.

Attachment A
Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Forms

1. Providers bill professional services on the CMS-1500 claim form.
2. Donor expenses are billed on the recipient claim.
3. Hospitals bill for services on the UB-92 claim form.

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Codes that are covered under the high dose chemotherapy and allogeneic stem cell support for genetic diseases and acquired anemias include:

38204	38205	38207	38208	38209	38230	86812
38240	38242	86813	86816	86817	86821	86822
96400	96405	96406	96408	96410	96412	96414
96420	96422	96423	96425	96440	96445	96450
96545	S2150	J9000 through J9999				

D. Providers must bill their usual and customary charges.